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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
HOLLINDEN, G	
ART UNIT	PAPER NUMBER
1616	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Claims 1 and 11-29 have been presented for examination and will be reviewed on their merits. The preliminary amendment, filed April 19, 1999, was entered prior to this examination on the merits. In said preliminary amendment were instructions to cancel claims 2-48 and add claims 49-67; however, the USPTO copy of the application file only contained ten claims, not forty-eight. Consequently, claims 2-10 were canceled and claims 49-67 were renumbered.

The numbering of claims is not accordance with 37 CFR § 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 CFR § 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 49-67 have been renumbered 11-29, respectively.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim 1 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "agent or cell". There is insufficient basis for this limitation earlier in the claim. For purposes of this examination, claim 1 is being treated as a method of treating a patient.

The treatment of exogenous organisms/ agents is first described and enabled in parent application 08/465,242. Therefore, the effective priority date of the claim designated invention is considered to be the filing date of '242, i.e. June 5, 1995.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent."

Claims 1 and 2-29 are rejected under 35 U.S.C. § 102(b,e) as being anticipated by Richter (5,484,803; PTO-1449 filed 4/19/99) and Wolf et al. (J. Am. Acad. Derm 31:678-680,1994; PTO-1449 filed 4/19/99).

These claims appear to be directed towards a method of treating a method of treating cells from an exogenous source (e.g. bacterial or fungal cells) using a precursor of protoporphyrin IX (e.g. 5-aminolevulinic acid).

Richter (col. 2, lines 14-36; claim 5) teaches that protoporphyrin precursors such as 5-aminolevulinic acid may be used to kill virus-containing cells, parasite-containing cells, bacteria, free viruses or other infectious agents. Wolf et al. (whole article) teach that 5-aminolevulinic acid may be used to treat fungi *in vivo*. Therefore, those claims generically drawn to any organism or to broad classes of organisms are anticipated.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1 and 2-29 are rejected under 35 U.S.C. § 103 as being unpatentable over Richter (5,484,803; PTO-1449 filed 4/19/99) and Wolf et al. (J. Am. Acad. Derm 31:678-680,1994; PTO-1449 filed 4/19/99).

These claims appear to be directed towards a method of treating a method of treating cells from an exogenous source (e.g. bacterial or fungal cells) using a precursor of protoporphyrin IX (e.g. 5-aminolevulinic acid).

Richter (col. 2, lines 14-36; claim 5) teaches that protoporphyrin precursors such as 5-aminolevulinic acid may be used to kill virus-containing cells, parasite-containing cells, bacteria, free viruses or other infectious agents. Wolf et al. (whole article) teach that 5-aminolevulinic acid may be used to treat fungi *in vivo*.

While Richter and Wolf et al. fail to teach all the possible exogenous organisms which would be encompassed by the claim designated invention, it would have been obvious to those of ordinary skill in the art that essentially any organism could be treated by 5-aminolevulinic acid because Richter and Wolf et al. teach that a wide and representative body of such organisms could be so treated. One of ordinary skill would have been motivated to use essentially any organism since Richter provides such an extensive list of possible organisms which may be treated.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claims 1 and 2-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. patent no. 5,955,490. Although the conflicting claims are not identical, they are not patentably distinct from each other because '490 teaches particular sub-genera and species of exogenous agents which are encompassed by the instant claims.

> The obviousness-type double patenting rejection, whether of the obviousness type or non-obviousness type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent[1].

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[1] *In re Thorington*, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 214 USPQ 761 (CCPA 1982); *In re Longi*, 225 USPQ 645 (CA FC 1985); and *In re Goodman*, 29 USPQ 2010 (CA FC 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

In view of the objections /rejections to the pending claims set forth above, no claims may be allowed at this time.

The processing of this application can be expedited by providing the following information or changes in your next amendment:

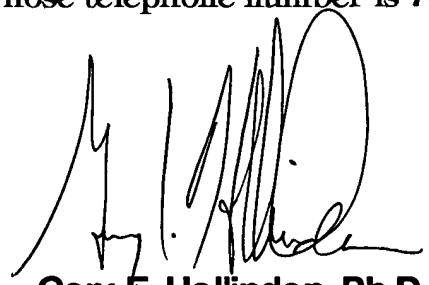
- Proper cross-reference to related applications for which priority is claimed under 35 U.S.C. § 120 in the first paragraph of the specification - including current status (M.P.E.P. 201.11)
- Early filing of an Information Disclosure Statement that includes a PTO-1449 form wherein the document number, publication date, inventor, country of publication, and US patent classification is listed for each patent document and wherein the author, title, journal, volume, issue (if known), pages, and year of publication is listed for all journal references (M.P.E.P. 609). A timely prior art disclosure by the Applicant aids in a speedy prosecution and helps to insure that the patent granted is both valid and enforceable.
- A descriptive title (M.P.E.P. 606 and 606.01). Please note that 1-2 word titles are generally unacceptable.
- Ensuring that each of the drawings presented (if any) are described in the brief description of the drawings. Please note that if a drawing has more than one figure in it (e.g. Figures 1A and 1B), each of the figures must be individually described.

  An abstract which is descriptive of the disclosed invention and contains the chemical structure of the active ingredient(s).
- Correction of any ambiguities in the specification which may lead to a printer inquiry, such as blank spaces which appear to be omissions.
- Correction of any typographical errors in the application.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to the Group 1600 fax machine at 703/308-4556. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30; November 15 1989.

Any inquiry concerning this Office Action or any earlier Office Actions in this application should be directed to Dr. Gary E. Hollinden whose telephone number is 703/308-4521. Dr. Hollinden's office hours are from 6:30 am to 3:00 pm on Monday through Friday.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is 703/308-1235.



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